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Primary Endpoint Met in Phase 3 Study of the Anti-PD-L1 Antibody Sugemalimab in Stage III Non-Small Cell Lung Cancer

Sugemalimab is the first PD(L)1 monoclonal antibody to demonstrate a progression-free survival benefit in Stage III non-small cell lung cancer (NSCLC) patients after treatment with either concurrent or sequential chemoradiotherapy
Positive results in both Stage III and Stage IV Phase 3 trials set the stage for regulatory discussions in multiple countries
EQRx, a company committed to developing and delivering important new medicines at lower prices, along with its partner CStone Pharmaceuticals, announced that the Phase 3 study evaluating sugemalimab, an anti-PD-L1 antibody, in Stage III NSCLC met its primary endpoint of prolonged progression-free survival. These results were disclosed after a planned interim analysis of GEMSTONE-301, a study investigating sugemalimab as consolidation therapy in patients with locally advanced, unresectable Stage III NSCLC without disease progression after either concurrent or sequential chemoradiotherapy. These findings, which were statistically significant and clinically meaningful, were determined by Blinded Independent Central Review (BICR) based on RECIST v1.1. Sugemalimab was well-tolerated and no new safety signals were observed. In stratified subgroup analyses, sugemalimab was associated with clinical benefit regardless of whether patients received concurrent or sequential chemoradiotherapy prior to sugemalimab.

Positive results were previously reported on the use of sugemalimab in Stage IV NSCLC at ESMO Asia 2020, demonstrating that sugemalimab plus standard-of-care chemotherapy prolonged PFS and was well-tolerated compared to chemotherapy regardless of PD-L1 expression level or histology. Together, these two positive Phase 3 studies position sugemalimab as a potential treatment option to address both Stage III and IV NSCLC.

“These encouraging results from both the Stage III and Stage IV studies suggest sugemalimab is a promising potential treatment option in a broad range of patient populations.” – Vincent Miller, MD, Physician-In-Chief

“Stage III NSCLC represents a heterogeneous group of patients with a wide range of therapeutic outcomes. Around the world, both sequential and concurrent chemotherapy are commonly used treatment approaches for this stage of disease,” said Vincent Miller, MD,

physician-in-chief at EQRx. “These encouraging results from both the Stage III and Stage IV studies suggest sugemalimab is a promising potential treatment option in a broad range of patient populations.”

“The PD(L)1 market is becoming more crowded, but the constant debate around pricing without action is to the detriment of patients. EQRx was created to address this challenge head-on by bringing high-quality medicines to patients at much lower prices,” commented Alexis Borisy, chief executive officer of EQRx. “PD(L)1 therapies are the backbone of cancer treatment, and we see tremendous opportunity for sugemalimab as a monotherapy or in combination regimens, lowering the overall costs of immunotherapy options.”

Specific study data will be presented at an upcoming medical conference.

EQRx and CStone Pharmaceuticals have partnered to expand global access to sugemalimab. The Companies plan to pursue regulatory discussions in multiple countries.

ABOUT LUNG CANCER

Every 15 seconds, a person across the world is diagnosed with lung cancer, and every 18 seconds, a person dies of the disease, making it the most commonly diagnosed cancer and the leading cause of cancer death worldwide. Lung cancer is the second most commonly diagnosed cancer worldwide. In 2020, an estimated 2.2 million people were diagnosed with lung cancer.1 NSCLC is the most common type of lung cancer, accounting for 84% of all lung cancer diagnoses.

GEMSTONE-301 STUDY

GEMSTONE-301 study is a multicenter, randomized, double-blind Phase 3 clinical trial (clinicaltrials.gov registration number: NCT03728556; drug clinical trial registration number: CTR20181429), being conducted in China 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 study’s primary endpoint was PFS as assessed by BICR according to RECIST v1.1; the secondary endpoints included overall survival, PFS as assessed by the investigators and safety.

GEMSTONE-302 STUDY

GEMSTONE-302 (clinicaltrials.gov registration number: NCT03789604; drug clinical trial registration number: CTR20181452) is a randomized, double-blind, Phase 3 study of anti-PD-L1 monoclonal antibody sugemalimab plus platinum-based chemotherapy as first-line treatment for Stage IV squamous or non-squamous 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 study was conducted in China and the primary endpoint was investigator-assessed PFS. Secondary endpoints included overall survival, BICR-assessed PFS and safety.

In August 2020, the GEMSTONE-302 study met its primary endpoint and data was presented at ESMO Asia 20202, demonstrating that sugemalimab in combination with chemotherapy significantly prolonged PFS and reduced the risk of disease progression or death by 50% compared to placebo in combination with chemotherapy, as assessed by iDMC at the planned interim analysis. Subgroup analysis showed clinical benefit regardless of PD-L1 expression level or pathologic subtype in patients with Stage IV NSCLC. Sugemalimab in combination with chemotherapy was well tolerated, no new safety signals were identified. In November 2020, the National Medical Products Administration (NMPA) of China accepted the New Drug Application for sugemalimab combined with chemotherapy for the first-line treatment of advanced squamous and non-squamous non-small cell lung cancer patients.

ABOUT SUGEMALIMAB

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 stop. As a fully human, full-length anti-PD-L1 monoclonal antibody, sugemalimab mirrors the natural G-type immunoglobulin 4 (IgG4) human antibody, which reduce the risk of immunogenicity and potential toxicities in patients, a potential advantage during treatment.

Currently, sugemalimab is being investigated in a number of ongoing clinical trials. In addition to a Phase 1 study in the U.S., the clinical program in China includes one Phase 2 registration study for lymphoma (CS1001-201) and four Phase 3 registration studies in Stage III NSCLC, Stage IV NSCLC, gastric cancer, and esophageal cancer.

CS1001-201 is a single-arm, multicenter, Phase 2 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 for the treatment of T-cell lymphoma and Breakthrough Therapy Designation for the treatment of R/R ENKTL by the U.S. Food and Drug Administration. It has also been granted Breakthrough Therapy Designation by the NMPA of China. The proposed indication is R/R ENKTL.

EQRx holds the development and commercialization rights to sugemalimab outside of Greater China.

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, the Company 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.

To learn more, visit www.eqrx.com and follow us on social media: Twitter: @EQRxInc, LinkedIn, Instagram: @eqrxinc.

About CStone

CStone Pharmaceuticals (HKEX: 2616) is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology 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.

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